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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,837	09/10/2002	Nikolaos S. Soukos	00786-421002	8657

7590 01/18/2006  
Fish & Richardson  
225 Franklin Street  
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EXAMINER

CAMERON, ERMA C

ART UNIT PAPER NUMBER

1762

DATE MAILED: 01/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/019,837

Applicant(s)

SOUKOS ET AL.

Examiner

Erma Cameron

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Response to Amendment*

#### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-18 and 22-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method in which the target material is coupled to the biofilm with a coupling medium, does not reasonably provide enablement for a method in which there is no coupling medium. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

See 8:21. This section of the specification says that the target material must be coupled to the biofilm by a coupling medium (emphasis added). The coupling medium, in other words, is a required aspect of the claimed invention.

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The examiner does not agree that a reading of page 8 would lead one to think that the target material must be coupled to the biofilm only when the stress wave is generated by irradiation.

3. Claims 1-4, 13-23 and 25-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method in which a target material is coupled to or disposed on the biofilm, does not reasonably provide enablement for a method that does not use a target material. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

See page 8. It appears that a target material is an essential aspect of the claimed invention.

The applicant has cited in the 12/12/2005 amendment a number of types of stress wave generators, but has not made it clear that these wave generators can be used without a target material. A reading of the specification leads one to believe that target materials are an essential part of the claimed invention.

4. Claims 1-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

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described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

a) 5:7: “capsular” has not been defined, and is therefore vague.

The applicant has stated that the term is known, but has not supplied a definition.

5. Claims 1-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

a) matrix of a biofilm (claims 1 and 24) is new matter.

The examiner finds only one example of the term “matrix” – 1:13 “matrix-enclosed”. It is not clear what is meant by matrix or matrix-enclosed.

b) enter the matrix (claim 24) is new matter.

The examiner cannot find in the specification the concept that the antimicrobial agent enters a “matrix” of a biofilm rather than the biofilm itself.

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6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 15, 19 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claims 15: “capsular polysaccharide” has not been defined, either in the claim or the spec, and is therefore vague and indefinite.

The one statement in the specification that the applicant refers to in the 12/12/2005 amendment offers very little in the way of clarification.

b) Claim 22: it is not clear what “associated” means. Does it mean that the biofilm is attached to the surface, near the surface, a part of the surface??

The section of the specification that the applicant refers to in the 12/12/2005 amendment offers very little in the way of answering the above questions.

c) Claim 19: the applicant has explained in the 12/12/2005 amendment that the use of the term “suitable” means that the medium is merely suitable for mixing with the compound.

This makes claim 19 unclear because it is not clear if the mixing actually occurs or not. If it does not occur, what is being claimed?

***Drawings***

8. The new sheet of drawings is acknowledged.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-6, 8, 10, 12-18 and 22-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flotte et al, Proceedings of the SPIE, 2681, pp 160-166, 1996.

Flotte teaches laser-induced stress transients (compressive pressure waves) that aid molecules crossing cell membranes by increasing cell permeability. The laser is at 193 nm, up to 750 bars and a rise time of 10-15 nseconds, and uses polyimide as a target (see entire document), thereby meeting the limitations of claims 1-6, 8, 10, and 24-26. The wavelength, pressure, and rise time overlap with that claimed by applicant.

The subject matter as a whole would have been obvious to one having ordinary skill in the art at the time the invention was made to have selected the overlapping portion of the range

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disclosed by the reference because overlapping ranges have been held to be a prima facie case of obviousness. See *In re Malagari* 182 USPQ 549.

Cells would be inclusive of the bacterial cells of a biofilm, and a biofilm would be inclusive of a variety of bacteria, fungi, protozoa and polysaccharide, as well a site, as in claims 14-18 and 22-23. The molecules that are induced to cross the cell membrane would be inclusive of the antimicrobial agent of claim 12 or claim 27.

The rapid heating of claim 12 would be inherent to the process.

The applicant has argued in the 12/12/2005 amendment that their claimed process delivers a compound to a matrix of a biofilm. However, the examiner finds only one place in the specification the term matrix is used – 1:13 “matrix-enclosed”. Nor has the applicant defined what is meant by a “matrix of a biofilm” and how that is the same or different from “matrix-enclosed”. The applicant further states that the matrix of a biofilm does not have a cell wall. However, the definition of biofilm (1:10-18) is “single or multiple bacterial species” and “microbial aggregates”. Bacteria have cell walls and therefore it is expected that biofilms have cell walls as part of their makeup.

11. Claims 7, 9, 11 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flotte et al, Proceedings of the SPIE, 2681, pp 160-166, 1996 taken in view of WO 98/23325.

Flotte is applied here for the reasons given above.

Flotte fails to teach all the details of claims 7, 9, 11 and 19-21.



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'325 teaches using laser-induced impulse transients to deliver compounds, such as therapeutic agents (15:24-34), to epithelial cells (the broad band, compressive laser stress waves have a rise time of 1-200 ns, a peak pressure of 300-200 bars (see page 4)).

'325 further teaches that a coupling medium, which may contain a surfactant of sodium lauryl sulfate (5:3-16), a target material of metal such as aluminum or copper or polystyrene (3:8-18, 12:29-13:9), a transparent material bonded to the target material (3:8-18, 13:10-24) and a reservoir of the coupling medium and compound (3:19-28) are used as part of the apparatus for generating laser stress waves.

It would have been obvious to one of ordinary skill in the art to have incorporated the apparatus of '325 into the Flotte process because of the teaching of '325 that theirs is conventional apparatus for generating laser-induced stress waves.

### *Conclusion*

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Erma Cameron whose telephone number is 571-272-1416. The examiner can normally be reached on 8:30-6:00, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
ERMA CAMERON  
PRIMARY EXAMINER

Erma Cameron  
Primary Examiner  
Art Unit 1762

January 15, 2006